



Dkt. #639-B-PCT-US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Nai-Kong CHEUNG

U.S. Serial No.: 10/621,027, continuation-in-part of International Application No. PCT/US02/01276, filed January 15, 2002, claiming benefit of U.S. Serial No. 60/261,911, filed January 16, 2001

Filed Date : July 16, 2003

For : THERAPY-ENHANCING GLUCAN

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April 12, 2004

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir/Madam:

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Applicants hereby submit this Supplemental Information Disclosure Statement in accordance with their duty of disclosure under 37 C.F.R. §1.56. Applicants originally filed an Information Disclosure Statement for the above-identified application on July 16, 2003. Applicants would like to direct the Examiner's attention to the following references which are listed below as **Exhibits 1-18** and on Form PTO/SB/08B (**Exhibit A**, 2 pages). Applicant would like to inform the Examiner that **Exhibits 3, 7, 12-13** are abstracts of the references. However, if the Examiner requires full-length references, immediately notify the Applicant's attorney's office. Further, Applicant's attorney's office may be contacted in the event that the Examiner would like a copy of all references filed with the July 16, 2003 Information Disclosure Statement. The following references are attached:

Applicants : Nai-Kong CHEUNG  
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Page : 2

1. S. Tsukagoshi, Y. Hashimoto, G. Fujii, H. Kobayashi, K. Nomoto, and K. Orita, Krestin (PSK). Cancer Treat. Rev. 11:131-155, 1984. **[Exhibit 1]**
2. H. Nanba and H. Kuroda, Antitumor mechanisms of orally administered shiitake fruit bodies. Chem. Pharm. Bull. (Tokyo) 35:2459-2464, 1987 **[Exhibit 2]**
3. Nanba, H., K. Mori, T. Toyomasu, and H. Kuroda, Antitumor action of shiitake (*Lentinus edodes*) fruit bodies orally administered to mice. Chem. Pharm. Bull. (Tokyo) 35:2453-2458, 1987. **[Exhibit 3]**
4. I. Hishida, H. Nanba, and H. Kuroda, Antitumor activity exhibited by orally administered extract from fruit body of *Grifola frondosa* (maitake). Chem. Pharm. Bull. (Tokyo) 36:1819-1827, 1988. **[Exhibit 4]**
5. H. Nanba and H. Kuroda, Potentiation of host-mediated antitumor activity by orally administered mushroom (*Agaricus bispora*) fruit bodies. Chem. Pharm. Bull. (Tokyo) 36:1437-1444, 1988. **[Exhibit 5]**
6. T. Ohmori, K. Tamura, A. Wakaiki, G. Kawanishi, S. Tsuru, T. Yadomae, and K. Nomoto, Dissociation of a glucan fraction (CO-1) from protein-bound polysaccharide of *Cordyceps ophioglossoides* and analysis of its antitumor effect. Chem. Pharm. Bull. (Tokyo) 36:4512-4518, 1988. **[Exhibit 6]**
7. H. Hanaue, Y. Tokuda, T. Machimura, A. Kamijoh, Y. Kondo, K. Ogoshi, H. Makuuchi, H. Nakasaki, T. Tajima, and T. Mitomi, Effects of oral lentinan on T-cell subsets in peripheral venous blood. Clin. Ther. 11:614-622, 1989. **[Exhibit 7]**
8. I. Suzuki, K. Hashimoto, N. Ohno, H. Tanaka, and T. Yadomae, Immunomodulation by orally administered  $\beta$ -glucan in mice. Int. J. Immunopharmacol. 11:761-769, 1989. **[Exhibit 8]**
9. I. Suzuki, T. Sakurai, K. Hashimoto, S. Oikawa, A. Masuda, M. Ohsawa, and T. Yadomae, Inhibition of

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U.S. Serial No.: 10/621,027  
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- experimental pulmonary metastasis of Lewis lung carcinoma by orally administered  $\beta$ -glucan in mice. *Chem. Pharm. Bull. (Tokyo)* 39:1606-1608, 1991. [Exhibit 9]
10. T. Sakurai, K. Hashimoto, I. Suzuki, N. Ohno, S. Oikawa, A. Masuda, and T. Yadomae. Enhancement of murine alveolar macrophage functions by orally administered  $\beta$ -glucan. *Int. J. Immunopharmacol.* 14:821-830, 1992. [Exhibit 10]
11. K. Hayakawa, K., N. Mitsuhashi, Y. Saito, M. Takahashi, S. Katano, K. Shiojima, M. Furuta, and H. Niibe, Effect of krestin (PSK) as adjuvant treatment on the prognosis after radical radiotherapy in patients with non-small cell lung cancer. *Anticancer Res.* 13:1815-1820, 1993. [Exhibit 11]
12. H. Hotta, K. Hagiwara, K. Tabata, W. Ito, and M. Homma, Augmentation of protective immune responses against Sendai virus infection by fungal polysaccharide schizophyllan. *Int. J. Immunopharmacol.* 15:55-60, 1993. [Exhibit 12]
13. H. Morinaga, K. Tazawa, H. Tagoh, A. Muraguchi, and M. Fujimaki, An in vivo study of hepatic and splenic interleukin-1 $\beta$  mRNA expression following oral PSK or LEM administration. *Gann* 85:1298-1303, 1984. [Exhibit 13]
14. Y. Iino, T. Yokoe, M. Maemura, J. Horiguchi, H. Takei, S. Ohwada, and Y. Morishita, Immunochemotherapies versus chemotherapy as adjuvant treatment after curative resection of operable breast cancer. *Anticancer Res.* 15:2907-2911, 1995. [Exhibit 14]
15. H. Nanba, Activity of maitake D-fraction to inhibit carcinogenesis and metastasis. *Ann. N. Y. Acad. Sci.* 768:243-245, 1995. [Exhibit 15]
16. V. Vetvicka, B.P. Thornton and G.D. Ross, Soluble  $\beta$ -Glucan Polysaccharide Binding to the Lectin Site of Neutrophil or Natural Killer Cell Complement Receptor Type2 (CD11b/CD18) Generates a Primed State of the Receptor Capable of Mediating Cytotoxicity of iC3b-

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Opsonized Target Cells. J. Clin. Invest., 98:50-61, 1996.

[Exhibit 16]

17. J. Yan, V. Vetvicka, Y. Xia, A. Coxon, M.C. Carroll, T.N. Mayadas and G.D. Ross,  $\beta$ -Glucan, a "Specific" Biologic Response Modifier That Uses Antibodies to Target Tumors for Cytotoxic Recognition by Leukocyte Complement Receptor Type 3 (CD11b/CD18)<sup>1</sup>. Clin. Invest., 163:3045-3052, 1999. [Exhibit 17]
18. Y. Xia, V. Vetvicka, J. Yan, M. Hanikyrova, T. Mayada and G.D. Ross, The  $\beta$ -Glucan-Binding Lectin Site of Mouse CR3 (CD11b/CD18) and Its Function in Generating a Primed State of the Receptor That Mediates Cytotoxic Activation in Response to iC3b-Opsonized Target Cells<sup>1</sup>. J. Immunology, 162:2281-2290, 1999. [Exhibit 18]

If a telephone interview would be of assistance in advancing prosecution of the subject application, Applicant's undersigned attorney invites the Examiner to telephone him at the number provided below.

No fee is deemed necessary in connection with the filing of this Supplemental Information Disclosure Statement. However, if any additional fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 50-1891.

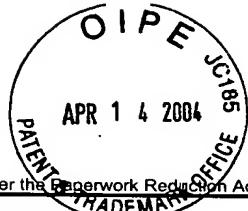
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Albert Wai-Kit Chan 4/12/09  
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Reg. No. 36,479

Respectfully submitted,

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PTO/SB/08B (04-03)

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Substitute for form 1449/PTO

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

**Complete if Known**

				Application Number	10/621,027
				Filing Date	July 16, 2003
				First Named Inventor	Nai-Kong CHEUNG
				Art Unit	
				Examiner Name	
Sheet	1	of	2	Attorney Docket Number	639-B-PCT-US

### NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	1	S. Tsukagoshi, Y. Hashimoto, G. Fujii, H. Kobayashi, K. Nomoto, and K. Orita, Krestin (PSK). Cancer Treat. Rev. 11:131-155, 1984.	
	2	H. Nanba, H. and H. Kuroda, Antitumor mechanisms of orally administered shiitake fruit bodies. Chem. Pharm. Bull. (Tokyo) 35:2459-2464, 1987.	
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Examiner Signature	Date Considered
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DC NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

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Substitute for form 1449/PTO				<b>Complete if Known</b>	
				<b>Application Number</b>	10/621,027
				<b>Filing Date</b>	July 16, 2003
				<b>First Named Inventor</b>	Nai-Kong CHEUNG
				<b>Art Unit</b>	
				<b>Examiner Name</b>	
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